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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,814	01/30/2004	Fanny Astruc	1034227-000667	6599

21839	7590	01/07/2008
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POST OFFICE BOX 1404		
ALEXANDRIA, VA 22313-1404		

EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
01/07/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Office Action Summary

**Application No.**

10/767,814

**Applicant(s)**

ASTRUC ET AL.

**Examiner**

Carlic K. Huynh

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 3, 13-18 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-12 and 19-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : 15 July 2005 and 09 October 2007.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-24 and 31 are pending in the application, with claims 25-30 having been cancelled, in response to the restriction requirement submitted on June 7, 2007. It is noted that claims 25-30 have been cancelled and new claim 31 has been added in a Response to Election/Restriction filed on October 9, 2007. Accordingly, claims 1-24 and 31 are being examined on the merits herein.

### ***Election/Restrictions***

2. Applicant's election without traverse of the claims of Group I, namely claims 1-24 and 31, in the reply filed on October 9, 2007 is acknowledged.

Claims 25-30 has been cancelled in the reply filed on October 9, 2007. Election was made without traverse in the reply filed on October 9, 2007.

3. Applicants' election with traverse of the election of species of: (1) DHEA as a DHEA, a chemical precursor of DHEA of formula (1) or a biological precursor of DHEA of formula (1); (2) propylene glycol as a dispersed hydrophilic phase; and (3) methicone copolyol as an emulsifier, in the reply filed on October 9, 2007 is acknowledged. The traversal is on the ground(s) that Examiner required election of an active ingredient from a group that does not include all of the active ingredients of claim 1, e.g. claim 14 names specific DHEA precursors which are not encompassed by formula (1) and claim 16 names specific DHEA derivatives which are not encompassed by formula (1).

Art Unit: 1617

Applicants' arguments were not found persuasive. The Examiner maintains and argues that there is a search burden for DHEA, a chemical precursor of DHEA of formula (1), or a biological precursor of DHEA of formula (1) because each DHEA, chemical precursor of DHEA of formula (1), or biological precursor of DHEA of formula (1) is structurally distinct from one another despite the fact that DHEA precursors and derivatives other than formula (1) was included in the species election. The Examiner also maintains and argues that there is a search burden for a dispersed hydrophilic phase because each dispersed hydrophilic phase is structurally distinct from one another. The Examiner further maintains and argues that there is a search burden for an emulsifier because each emulsifier is structurally distinct from one another.

Claims 3, 13-18, and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made with traverse in the reply filed on October 9, 2007.

Accordingly, claims 1-2, 4-12, and 19-24 are being examined on the merits herein.

Thus the election of species requirement is deemed proper and is made FINAL.

Claims 1-2, 4-12, and 19-24 are directed to a stable, recrystallization-resistant invert emulsion and thus intended use is not given any patentable weight.

#### ***Priority***

4. Acknowledgment is made of applicant's claim for foreign priority based on and application filed in France on August 2, 2001.

Art Unit: 1617

### ***Information Disclosure Statement***

The Information Disclosure Statements submitted on July 15, 2005 and October 9, 2007, are acknowledged.

### ***Oath/Declaration***

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It does not identify the citizenship of each inventor. It is noted that "French" is not a proper country but a language. Appropriate correction is required.

### ***Specification***

6. The use of the trademarks 3-acetoxy-7-benzoate DHEA, Abil, 3225C Formulation Aid, Wacker SPG 128 VP, Silwax, and Arlacel P 135 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Art Unit: 1617

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 1-2, 4-12, and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piazza et al. (US 5,565,439), Luther et al. (US 6,235,271), Baldo et al. (WO 01/26618 A2), Afriat et al. (US 5,935,588 as cited in the IDS), and Vennat et al. (Drug Development and Industrial Pharmacy, 1998, Vol. 24, No. 3, pp. 253-260).

It is noted that a cursory translation of Baldo et al. (WO 01/26618 A2) is used for citation purposes. A full translation will be provided at a later time.

Applicants have disclosed their invention as invert emulsions, which they have defined as “perfectly stable” in terms of size of the globules and viscosity (see page 8, paragraph [0039] of the specification). Moreover, Applicants have also disclosed that “the preparation of the emulsions according to the invention was found to require little mechanical or thermal energy

Art Unit: 1617

compared with the preparations of other invert emulsions already known" (see page 21, paragraph [0088] of the specification).

It is also noted that the dispersed hydrophilic phase of the instant invention may be exclusively glycolic (see page 12, paragraph [0048] of the specification).

Piazza et al. teach emulsion skin care preparations of the oil-in-water type comprising dehydroepiandrosterone, sunscreen, and propylene glycol (column 10, lines 64-65; column 13, lines 17-18; column 17, line 67; column 18, line 1; and column 22). It is noted that dehydroepiandrosterone is known in the art as DHEA. DHEA is about 0.001% to about 2% of the composition, which meets the limitation of the weight of DHEA as recited in instant claims 19-20 and 22 (column 18, line 7). Piazza et al. further teach various pharmaceutically-acceptable carriers, which include water and propylene glycol, which may comprise from 0.1% to 99.99999% by weight of the composition (column 7, lines 16 and 44-46). Thus it would be obvious the composition contains 50% water as recited in instant claim 24. It would also be obvious that propylene glycol is from 30% to 100% by weight of the composition as recited in instant claim 22. Piazza et al. also teach vitamins may also be included in the composition (column 12, lines 34-35).

Piazza et al. does not teach a lipophilic continuous phase, an oil-in-water emulsion having the appropriate water activity, and the coemulsifier cetearth-20.

Luther et al. teach a sunscreen composition of the oil-in-water type comprising the UV absorber 4-isopropylbenzylsalicylate and propylene glycol (column 12, line 44; column 14, line 66-67; and column 18, lines 5-20).



Art Unit: 1617

Baldo et al. is used solely to demonstrate that liposoluble UV filters such as 4-isopropylbenzylsalicylate provides a means of preventing or delaying the crystallization of dehydroepiandrosterone in compositions containing 4-isopropylbenzylsalicylate and dehydroepiandrosterone (abstract; and page 3, line 8). Thus it would be obvious that compositions containing dehydroepiandrosterone and 4-isopropylbenzylsalicylate provides for the prevention or delay of crystallization of dehydroepiandrosterone.

Afriat et al. teach a water/oil/water triple emulsion containing at least a silicone emulsifier and having a water activity of less than or equal to 0.75 (abstract; column 2, lines 16-17; and column 3, lines 3-4). The silicone emulsifier is from 0.5 to 8% by weight of the emulsion, which meets the limitation of the emulsifier is "from 0.5% to 8% by weight" of the emulsion as recited in instant claim 22 (column 4, lines 55-58). Since alkyl methicone copolyol is a well known silicone emulsifier, it would be obvious that alkyl methicone copolyol is the silicone emulsifier. Moreover, it would be obvious that the species of alkyl methicone copolyol would have an HLP ranging from 2 to 7. Afriat et al. also teach creams for the protection, treatment, or care of the face, hands or feet (column 5, lines 62-63). The cream for the skin contains propylene glycol (column 7, lines 5-25). It would obvious that the protection, treatment, or care of the face, hands or feet can be a sunscreen protection.

Vennat et al. teach that Eumulgin B<sub>2</sub> is an emulsifier used in oil-in-water type emulsions (page 257 and Table 4). Eumulgin B<sub>2</sub> is known in the art as cetareth-20. Cetareth-20 is 1.5% by weight of the composition, which meets the limitations of "up to 5% by weight of a coemulsifier" as recited in instant claim 23 (page 258, Table 4). Moreover, it would be obvious

Art Unit: 1617

that the ultimate species of coemulsifiers, namely cetareth-20, would have an HLB greater than 6.

Since Afriat et al. teach various emulsifiers and since Vennat et al. teach cetareth-20 is an emulsifier that can be used in oil-in-water type emulsions, it would be obvious to use cetareth-20 in the emulsion of the instant application.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the composition of Piazza et al. to contain 4-isopropylbenzylsalicylate because the composition of Luther et al. teaches 4-isopropylbenzylsalicylate and according to Luther et al., 4-isopropylbenzylsalicylate is used as a sunscreen.

The motivation to combine the compounds of Piazza et al. to the compounds of Luther et al. is that the compositions of Luther et al. are compositions of 4-isopropylbenzylsalicylate and that such compositions can be used as sunscreens.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the composition of Piazza et al. and Luther et al. to contain alkyl methicone copolyol and cetareth-20 because the composition of Afriat et al. teaches alkyl methicone copolyol and the composition of Vennat et al. teaches cetareth-20 and according to Afriat et al. alkyl methicone copolyol is used as an emulsifier in oil-in-water compositions and according to Vennat et al. cetareth-20 is used as an emulsifier in oil-in-water compositions.

The motivation to combine the compounds of Piazza et al. and Luther et al. to the compounds of Afriat et al. and Vennat et al. is that the compositions of Afriat et al. are alkyl

Art Unit: 1617

methicone copolyol and the compositions of Vennat et al. are cetareth-20 and that such compositions are used as emulsifiers in oil-in-water compositions.

It is noted that “It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose” and “It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose”. *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Regarding “invert emulsions” as recited in claims 1-2, 4-12, and 19-24, Applicants have disclosed their invention as invert emulsions, which they have defined as “perfectly stable” in terms of size of the globules and viscosity (see page 8, paragraph [0039] of the specification) and that “the preparation of the emulsions according to the invention was found to require little mechanical or thermal energy compared with the preparations of other invert emulsions already known” (see page 21, paragraph [0088] of the specification). Thus it would be obvious that one of ordinary skill in the art would be able to formulate an invert emulsion of the instant invention.

### ***Double Patenting***

#### **Obviousness-Type**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Art Unit: 1617

*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 19-20, and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 8 of copending Application Simonnet (10/484,428).

The instant claims 1, 19-20, and 22 are directed to an emulsion comprising DHEA, a glycolic or hydroglycolic dispersed hydrophilic phase, a lipophilic continuous phase, and an emulsifier having an HLB ranging from 2 to 7 where the emulsion is from 0.001% to 20% or from 0.001% to 5% or from 0.2% to 4% by weight of DHEA.

Claims 1-2 and 8 of Simonnet are directed to a composition consisting essentially of DHEA, where DHEA is from 0.1 to 5% by weight of the composition.

Given the broadest interpretation of claims 1-2 and 8 of Simonnet, the composition of DHEA may also contain a glycolic or hydroglycolic dispersed hydrophilic phase, a lipophilic continuous phase, and an emulsifier having an HLB ranging from 2 to 7 due to the open language of "consisting essentially of". "By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A consisting essentially of claim occupies a middle ground between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising format." *PPG*

Art Unit: 1617

*Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998).

Thus the composition consisting essentially of DHEA is not patentably distinct between Simonnet and the instant application.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

9. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application Astruc et al. (11/196,301).

The instant claim 1 is directed to an emulsion comprising DHEA, a glycolic or hydroglycolic dispersed hydrophilic phase, a lipophilic continuous phase, and an emulsifier having an HLB ranging from 2 to 7.

Claim 1 of Astruc et al. is directed to a cosmetic/dermatological composition comprising an emulsion of at least one active agent solubilized in a glycolic or hydroglycolic dispersed hydrophilic phase, a lipophilic continuous phase and an emulsifier having an HLB ranging from 2 to 7.

Given the broadest interpretation of claim 1 of Astruc et al., it would be obvious that the active agent can be DHEA.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Art Unit: 1617

***Conclusion***


10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

  
**SHENGJUN WANG**  
**PRIMARY EXAMINER**